REMARKS

Initially, Applicants would like to express appreciation to the Examiner for the detailed Official Action provided.

Claims 1-7 and 10-17 are currently pending. Applicants respectfully request reconsideration of the outstanding rejections and allowance of claims 1-7 and 10-17 in the present application. Such action is respectfully requested and is now believed to be appropriate and proper.

Claims 1, 2, 4-7, and 10-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over LIPKOVER (U.S. Patent No. 5,421,816) in view of SHIMADA et al. (U.S. Patent No. 5,267,985), KOST et al. (U.S. Patent No. 4,767,402), and HIDAKA et al. (U.S. Patent No. 4,990,340).

However, Applicants note that LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al. fail to teach or suggest the subject matter claimed in independent claims 1, 7, and 14-17. In particular, claim 1 sets forth an ultrasonic percutaneous penetration device including, inter alia, an irradiation unit including a first ultrasonic transducer and a second ultrasonic transducer; and a control unit that controls irradiation conditions of the irradiation unit; "wherein the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz; and wherein the active ingredient is at least one active ingredient selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract". Claim 7 sets forth an ultrasonic percutaneous penetration kit including, inter alia, a medicine containing an active ingredient; an irradiation unit including a first ultrasonic transducer and a second ultrasonic transducer; and a control unit; "wherein the control unit controls the frequency of the ultrasonic waves to a

frequency within a range from 3 to 7 MHz; and wherein the active ingredient is at least one active ingredient selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract". Claims 14-17 each set forth an ultrasonic percutaneous penetration method including, inter alia, contacting a skin surface with a medicine, and applying ultrasonic waves, providing an irradiation unit including a first transducer and a second ultrasonic transducer; and providing a control unit; "wherein the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz; and wherein the active ingredient is at least one active ingredient selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract".

The LIPKOVER patent discloses an ultrasonic transdermal drug delivery system including a medicine, an irradiation unit, and a control unit. As recognized by the Examiner, the LIPKOVER patent fails to teach or suggest a second transducer that generates waves at a second frequency, and a control unit that controls first and second transducers, a frequency in the range of 3 MHz to 7 MHz, and an active ingredient selected from the group vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract.

The SHIMADA et al. patent is directed to a drug delivery system that includes a second transducer and a voltage source that controls the transducers. However, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a). Moreover, as recognized by the Examiner, SHIMADA et al. fails to teach or suggest a control unit that controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz.

The KOST et al. patent is directed to ultrasound transdermal drug delivery that includes ultrasound having a frequency within a range of 0.2 MHz to 10 MHz. However, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the *further* modification suggested by the Examiner in the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a).

Further, KOST et al. fails to teach or suggest controlling the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz. In this regard, Applicants' note that KOST et al. teaches providing a frequency within a range of 0.2 MHz to 10 MHz.

The Examiner has contended that selecting a specific frequency would have been obvious to one having ordinary skill in the art, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

Initially, Applicants respectfully submit that the general conditions of the claims are not disclosed in the prior art. In this regard, it is noted that the range taught by KOST et al., i.e., 0.2 MHz to 10 MHz, does not represent the general conditions of the prior art, nor has the Examiner proffered any evidence to suggest the same. Accordingly, it is respectfully submitted that, contrary to the Examiner's assertions, the general conditions of the prior art are not shown.

Further, Applicants respectfully submit that the claimed frequency range is not the mere discovery of optimum or working ranges that involves only routine skill in the art. In this regard, it is noted that Applicants' claimed invention provides that the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz. The ultrasonic wave frequency within the range of 3 to 7 MHz allows the medicine to effectively penetrate a target in a shallow portion from the skin surface. See particularly page 10 of Applicants'

specification. Accordingly, the ultrasonic frequency range of 3 to 7 MHz of Applicant's claimed invention provides distinct advantages over the prior art. Accordingly, it is respectfully submitted that, contrary to the Examiner's assertions, claimed frequency range of 3 to 7 MHZ is not the mere discovery of a range involving only routine skill in the art.

Further, KOST et al. does not teach providing a *first* and a *second* transducer, nor providing a first and a second transducer and controlling the frequencies of *both* of the transducers so that the *frequencies* are within the range of 3 to 7 MHz.

Therefore, in view of all of the above, the KOST et al. patent fails to cure the deficiencies of the LIPKOVER device and method.

The HIDAKA et al. patent is directed to a sustained release pharmaceutical preparation including the use of glutathione transferred transdermally for use as an antidote. However, the HIDAKA et al. patent fails to teach or suggest providing ultrasonic waves to enhance the transdermal transfer of the glutathione. HIDAKA et al. also fails to teach or suggest selecting an active ingredient from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract. Moreover, HIDAKA et al. also fails to teach or suggest selecting an active ingredient to obtain a desired effect of whitening, wrinkle reduction, slimming, or trichophytosis treatment. Clearly, then, HIDAKA et al. teaches neither the claimed active ingredient selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract; nor the resulting advantages thereof, as in Applicants' invention. Therefore, the HIDAKA et al. patent fails to cure the deficiencies of the LIPKOVER device and method.

Moreover, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a.

Therefore, as described in detail above, SHIMADA et al., KOST et al., and HIDAKA et al., in combination, fail to teach or suggest the claimed combinations as set forth in claims 1, 7, and 14-17. Therefore, the SHIMADA et al., KOST et al., and HIDAKA et al. patents fail to cure the deficiencies of the LIPKOVER device and method, and even assuming, arguendo, that the teachings of LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al. have been properly combined, Applicants' claimed ultrasonic percutaneous penetration device, kit, and method would not have resulted from the combined teachings thereof.

Further, as described in detail above, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modifications suggested by the Examiner in the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a) over LIPKOVER in view of SHIMADA et al., KOST et al., and HIDAKA et al. Thus, the only reason to combine the teachings of LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al. results from a review of Applicants' disclosure and the application of impermissible hindsight. Accordingly, the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a) over LIPKOVER in view of SHIMADA et al., KOST et al., and HIDAKA et al. is improper for all the above reasons and withdrawal thereof is respectfully requested.

Applicants submit that dependent claims 2, 4-6 and 10-13, which are at least patentable due to their dependency from claims 1 and 7 for the reasons noted above, recite additional features of the invention and are also separately patentable over the prior art of record based on the additionally recited features.

Claim 3 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over LIPKOVER in view of SHIMADA et al., KOST et al., and HIDAKA et al., and further in view of ROWE et al. (U.S. Patent No. 6,234,990).

Applicants note that LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al. fail to teach or suggest the subject matter claimed as set forth in independent claim 1, as described above. Further, ROWE et al. fails to cure these deficiencies. Thus, even if the teachings of LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al., and ROWE et al. were combined, as suggested by the Examiner, the claimed combination would not result. Moreover, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claim 3 under 35 U.S.C. § 103(a) over LIPKOVER in view of SHIMADA et al., KOST et al., and HIDAKA et al., and further in view of ROWE et al. Thus, the only reason to combine the teachings of LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al., and ROWE et al. results from a review of Applicants' disclosure and the application of impermissible hindsight. Accordingly, the rejection of claim 3 under 35 U.S.C. § 103(a) is improper for all the above reasons and withdrawal thereof is respectfully requested.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection, and an early indication of the allowance of claims 1-7 and 10-17.

SUMMARY AND CONCLUSION

In view of the foregoing, it is submitted that the present response is proper and that none of the references of record, considered alone or in any proper combination thereof, anticipate or render obvious Applicants' invention as recited in claims 1-7 and 10-17. The applied references

of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Accordingly, consideration of the present response, reconsideration of the outstanding Official Action, and allowance of all of the claims in the present application are respectfully requested and now believed to be appropriate.

Applicants have made a sincere effort to place the present application in condition for allowance and believe that they have now done so.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
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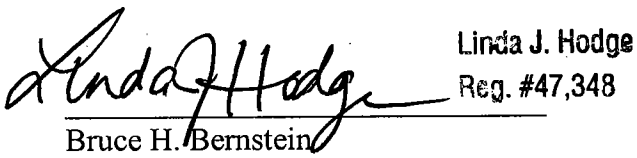

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